

**BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK LLC
SYRACUSE UNIVERSITY
ASSENT FORM - Children Ages 9-15 Years**

Protocol Title: Biofeedback-Enhanced Treatment for Speech Sound Disorder: Randomized Controlled Trial and Delineation of Sensorimotor Subtypes

Protocol #: C-RESULTS-RCT, sub-study 1

Sponsor: National Institutes of Health (NIH) National Institute on Deafness and Other Communication Disorders (NIDCD)

Principal Investigator: Dr. Jonathan Preston

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Why is the study being done?

- You are being invited to participate in a research study because you have difficulty saying the English “r” sound.
- We will test different types of therapy that use pictures made by computers based on your “r” sound.
- We want to find out what method of therapy works best for most people.
- You can say "Yes" or "No" to being in this study.
- You can ask as many questions as you like before you decide.
- About 180 other children will be in this study at 3 sites.

What will happen if you are in this study?

If you choose to be evaluated for our study, we will test your hearing, language, speech, and thinking skills. We will ask you to say the “r” sound in different words and sentences. The evaluation may last up to 3 sessions.

If you enroll in the study, we will ask you to come for 2-3 treatment sessions per week for approximately 10 weeks. You will start in an “intensive” phase where we will ask you to come in three times a week for sessions that last about one and a half to two hours. This will last about two weeks. For the rest of the study, we will ask you to come in twice a week for sessions that last about 45 minutes. This will last about eight weeks.

After the first phase of treatment, we will use random assignment (like flipping a coin) to determine which type of treatment you will receive. Based on this assignment, your clinician may work with you using verbal and auditory models and cues, or a computer, or an ultrasound device.

After you finish the treatment part of the study, we will ask you to come in to complete some additional tests of your speech perception and production. You may be invited to return for an optional final session approximately 1 – 2 hours in duration.

We will make audio recordings of you during testing and therapy sessions. *If you*

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participate in ultrasound treatment: We will collect video recordings of you as part of this study. We use these recordings to check whether study staff are consistent in following our standard study procedures. We will not release video of you without your permission.

Can you get hurt in the study?

There is no risk from participating in this study beyond that of everyday life. *If you participate in ultrasound treatment:* Our ultrasound machine is safe for kids to use. No one has been hurt by using this kind of ultrasound to look at tongue movements. When you use the ultrasound machine, you can take a break whenever you want. We clean our equipment every time we use it. In one task, we will ask you to say some words while listening to a loud noise. You can tell us if the noise is too loud for you and we will turn it down.

Will this study help you?

Participating in this study may help you make a better “r” sound. However, it is also possible that being in this study might not help you. But we hope that this study will help other children who have trouble saying the “r” sound in the future.

Who will know that you are in this study?

To protect your privacy, when we collect data for this study, we do not include things that could identify you like your name or birthdate. We store study materials in safe places like a locked cabinet or a password-protected database.

We ask outside listeners (untrained individuals recruited to complete speech rating tasks in our lab or on the internet) to listen to recordings from our study and rate the accuracy of each “r” sound. When we do this, we mix together recordings of you saying words or sentences with recordings of other kids saying the same words or sentences. The listeners will not know your name or anything else about you.

Below, we will ask for your permission to share recordings of your speech as part of future studies. We will also ask if you will allow us to share audio or video recordings of you with other speech therapists and students who are learning to be speech therapists. You are free to say no. No one outside of the study can listen to these recordings unless you give your permission.

